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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/677,737	10/02/00	COLE	C JBP525

HM12/0523

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EXAMINER
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YU, G

ART UNIT

PAPER NUMBER

1619

DATE MAILED:

05/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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1- File Copy

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/677,737	COLE ET AL.	
Examiner	<b>Art Unit</b>		
Gina C Yu	1619		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

THE MAILING DATE OF THIS COMMUNICATION IS [REDACTED].

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 14 May 2001.

2a)  This action is **FINAL**.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-16 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

15)  Notice of References Cited (PTO-892)  
16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.

18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_  
19)  Notice of Informal Patent Application (PTO-152)  
20)  Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 13 are vague and indefinite because the term "dimethylaminoethanol" lacks antecedent basis.

Claims 7 and 16 are rejected because the phrase "derivatives thereof" renders the claims vague and indefinite. It is not clear from the specification as to how to ascertain the scope of the "derivatives" of alpha-hydroxy acids. Similarly, the term "natural plant extracts" is also not clearly defined in the disclosure and renders the claims vague and indefinite.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(A) Claims 1-16 are rejected under 35 U.S.C. § 102 (a) and (e) as anticipated by U.S. Pat. No. 6,162,419 issued to Perricone.

‘419 describes topical ascorbyl compositions for treating and/or preventing sunburn. See abstract; col. 1, line 4- col. 3, line 8. The solvents for the composition comprise 0.1 – 5% by weight of dimethylaminoethanol and up to about 10 % by weight of tyrosine. See col. 3, line 10 – 51; col. 5, line 35 – col. 6, line 12. The reference also illustrates the examples of formulation for cream and gel. See Examples in columns 7 – 12. The composition in the examples comprise the skin irritating ingredients including glycolic acid, urea, titanium dioxide, grapeseed and green tea extract which are encompassed by the instant claims 6, 7, and 16. See Example 1, Formulation 3; col. 6, lines 13 – 44. It is further disclosed that the composition may be incorporated in soaps and cleaners that come in contact with skin when used. See col. 5, lines 8 – 18.

It is examiner’s position that the limitation of claims 1 and 11 that the composition is used for ameliorating redness or inflammation of skin, and irritating effects caused by irritant in the composition anticipated because the claimed function of the composition is inherent. For claims 8-10, ameliorating the inflammation due to contact with soaps or cleansers, rosacea, atopic dermatitis, or allergic skin reactions is also an inherent property of the composition disclosed in ‘419.

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(B) Claims 1-16 are rejected under 35 U.S.C. § 102 (b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Pat. No. 5,643,586 issued to

Perricone.

‘586 describes method to treat aged skin and subcutaneous muscle by applying topical compositions containing 0.1 – 10 % by weight of catecholamine precursors. Tyrosine is a preferred catecholamine precursor in this invention. See abstract; col. 4, lines 7 - 34. The reference further teaches adding into the composition 3 % by weight of acetylcholine enhancer, preferably dimethylaminoethanol. See claim 4. Claims 7 and 16 in the instant application are rejected by the disclosure that the composition may also be formulated with alpha-hydroxy acids along with tocotrienol. See col. 7, lines 30-41.

Although the reference is not specifically directed to the application of the composition on the skin affected with inflammation, it is disclosed in the reference that the composition may be formulated and used as anti-inflammatory. See col. 9, lines 11 – 65. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have adapted the composition in Perricone to use it for inflammatory skin disease, as suggested by the reference.

#### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-305-3593. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu  
Patent Examiner  
May 21, 2001



DIANA DUDASH  
SUPERVISORY PATENT EXAMINER  
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